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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,466	03/02/2000	James L. Hartley	0942.4680003/RWE/BJD	4289

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EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	18

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/517,466	Applicant(s) HARTLEY ET AL.	
	Examiner Diana Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 26-34, and 36-38, drawn to nucleic acid molecules, primers, vectors, host cells, and kits, classified in class 536, subclasses 23.1, 24.1, and 24.33, and class 435, subclasses 252.3, 320.1, 325, and 810.

II. Claims 22-24, drawn to methods of nucleic acid synthesis and amplification, classified in class 435, subclasses 91.2 and 91.5.

III. Claims 25 and 35, drawn to polypeptides, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are patentably distinct because the Inventions are drawn to materially distinct products having different structures and functions. The nucleic acids of Invention I are composed of nucleotides linked by phosphodiester bonds, and function in methods such as nucleic acid hybridization. The polypeptides of Invention III are composed of amino acids linked by peptide bonds, and are function in methods such as methods of making antibodies or methods of detection protein binding. Accordingly, Inventions I and III are distinct from one another.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Invention I may be used in a variety of materially different processes, such as methods of cloning, methods of nucleic acid sequencing, etc.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and the polypeptides of Invention function in methods that are materially distinct from the nucleic acid synthesis and amplification methods of Invention II, such as methods of making antibodies or methods of detection protein binding.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-III require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

3. If applicant elects either Group I or Group III, applicant is required to further elect a single patentably distinct nucleic acid or polypeptide. **This is not an election of species.** By statute, "[i]f two or more independent and distinct

inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Inventions I and III encompass multiple distinct nucleic acids and polypeptides that are structurally distinct chemical. These molecules are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid or polypeptide is presumed to represent an independent and distinct invention, subject to restriction pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

Should applicant traverse on the grounds that the different species encompassed by Inventions I and III are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

With particular respect to Group I it is noted that the claims of Group I encompass several distinct *att* nucleic acids as set forth together in claim 1 and separately in dependent claims 2-9, as well as primers "for amplifying" these nucleic acids (claims 15-18), vectors and host cells comprising these nucleic

acids (claims 19-21), and kits comprising these reagents (claims 36-38). Group I also encompasses the *att* nucleic acids comprising mutations of claims 26-32, including the 6 distinct SEQ ID NOS set forth in claims 30-32, as well as a variety of particular vectors and host cells (claims 33-34), and kits comprising these reagents (claims 36 and 38). In response to this requirement, applicants should identify the species that is elected consonant with the requirement, and a listing of all claims readable thereon, including any claims subsequently added. Further, for those claims readable on the elected invention that recite additional particular molecules that include the elected species (e.g., claim 33, any of claims 30-32), applicants should identify those particular molecules that correspond to the elected invention. For example, if the species elected by applicants is contained within vector(s) of claim 33 and/or comprises particular SEQ ID NOS of claims 30-32, applicants should identify which of the particular vectors of claim 33 comprise the elected nucleic acid, which (if any) of the particular SEQ ID NOS in claims 30-32 correspond to the elected nucleic acid, etc.

With further respect to Group III, it is noted that the claims of Group III encompass polypeptides encoded "by the isolated nucleic acid molecule of any one of claims 1-10" (see claim 25) as well as a polypeptides "encoded by the vector of claim 33" (see claim 35). In responding to this requirement, applicants should identify the particular species of polypeptide that is elected consonant with this requirement (e.g., a polypeptide encoded by "an attB1 nucleotide sequence as set forth in Figure 9"), and, if applicable, further identify those

particular molecules encompassed by claim 35 that correspond to the elected polypeptide (i.e., identify the vectors of claim 33 that encode polypeptides corresponding to the elected species).

4. This application also contains claims directed to the following patentably distinct species of the claimed invention: the multiple species of "functional or structural nucleotide sequences" recited in claims 10-14. The claims encompass "one or more" of the recited species, and therefore encompass embodiments of the claimed invention in which the recited elements are present singly or in any possible combination with one another, such that the claims encompass numerous distinct species of nucleic acid molecules having different structural and functional elements.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species – i.e., a single one of the recited sequences or a single combination of sequences encompassed by the claims -- for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form

or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
March 23, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600